DRUG CRITERIA and LIMITS

The pages which follow describe conditions of coverage and limits for the drugs listed. This list is updated by Medicaid Information Bulletins.

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ATTACHMENTS

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Atypical Antipsychotic ICD.9 Codes
- Age Group, 6 Years or less
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Explanation of Table Headings

LIMIT	Drug has a cumulative limit approved by the Drug Utilization Review (DUR) Board for any 30-day period. Drug does not qualify for early refills. Additional information on page 3.
COMMENTS	Indicates other pertinent information for the drug. Units are cc's for liquids = 1:1 tablets, capsules = 1:1 powders are usually grams to cc's to units 1:1
AGE	When this column is blank, Medicaid covers the item from birth through any age. If there are age limits either for a drug or for drug usage based on diagnosis, the age range is entered numerically. The patient's age on the date of service must be within the age range specified. For example, "0 - 20" means for ages from birth through age 20.
DIAGNOSIS	This is the diagnosis or diagnoses for which the drug may be approved. The criteria and age limits for authorization may vary with the diagnosis.
CRITERIA & INSTRUCTIONS	Specific information required by Medicaid before the item will be reimbursed. All criteria listed must be met, unless otherwise specified.
P A	**P**rior **A**uthorization is required by Medicaid when either of the following codes is entered in this column: **T** - Telephone Prior Authorization **W -** Written Prior Authorization. The pharmacist must obtain the prior authorization from Medicaid, unless noted otherwise, and write the authorization number on the prescription. When the P A column is blank, prior authorization is not required. References: Utah Medicaid Provider Manual for Pharmacy Services, SECTION 1, GENERAL INFORMATION, Chapter 6, Prior Authorization; SECTION 2, PHARMACY SERVICES, Chapter 2, Prior Approval; Chapter 4, Coverage Limitations; and Chapter 5, Special Drug Provisions.

How changes are marked on the Drug Criteria and Limits List

A vertical line in the margin indicates where text on a page has changed or been added.

An asterisk (*) marks where text has been removed.

Drugs with Limits (No Prior Authorization)

In accordance with the Utah Medicaid Provider Manual for Pharmacy Services, SECTION 2, Chapter 4 - 9, Limits on Certain Drugs, some drugs are limited by quantity in any 30-day period. The drugs listed in the table below have a cumulative limit and do not qualify for early refills under Chapter 4 - 7, Early Refills. The limits are those approved by the Drug Utilization Review (DUR) Board. Physicians and other prescribers who feel that a patient has specific needs which exceed the limits may appeal to the DUR Board. All medications remain subject to all other requirements of the Utah Medicaid Pharmacy Program, as described in the Utah Medicaid Provider Manual for Pharmacy Services.

DRUG	LIMIT	COMMENTS	EFFECTIVE DATE
Celebrex, Vioxx	Limit: 60 per 30 days		November 1, 1999
Carisoprodol	Limit: 120 (1 tablet q6h dosing) tablets in any 30-day period		January 1, 1999
Preven - "morning after pill" NDC 63955001001	Limit: two kits in any 30-day period		November 12, 1998

*

DRUG	LIMIT	COMMENTS	EFFECTIVE DATE
Schedule II & III analgesics: -Propoxyphene/APAP - hydrocodone/APAP - Codeine/APAP - Oxycodone/APAP	Limit: 180 in any 30-day period	Narcotic analgesics in combination with ASA or ibuprofen are not included in this restriction. Liver toxicity occurs at APAP levels of 4 gms per day if taken on a routine basis.	January 1, 1999
Stadol	Limit: four vials in any 30-day period. (4 vials x 2.5 ml = 10 units)	The limit is due to frequent over-usage.	March 1, 1997
'Triptans' for Migraines: any combination of the following: - Amerge® - Maxalt® - Zomig® - Imitrex®	Limit: 9 units per month per client		effective July 1, 2002
Ultram	Limit: 180 tablets in any 30-day period	Ultram is a non-scheduled drug for pain. Because of information concerning addicting properties for this drug, a monthly quantity limit was established.	March 1, 1997
Viagra	Limit: five tablets in any 30-day period for any combination of the three strengths: 25mg, 50mg, and 100mg	In addition to the limit on tablets, the patient must be male, and the minimum age is 18.	September 1, 1998
Miralax	Limit: cumulative limit of 1054 gms/31 days.	Quantities in excess of 1054 gm will require a petition to the DUR Board.	July 1, 2002

Drugs Requiring Prior Authorization

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Lactulose (Chronulac, Cephulac)		❶ Chronic liver failure ❷ Hepatic encephalopathy ❸ Chronic portal hypertension	Lactulose is approved for 60ml per day without prior approval. This will be based on a cumulative 30 day limit. For quantities in excess of 60ml per day, prior approval is required. One of the following documented conditions must exist : 1. Chronic liver failure 2. Hepatic encephalopathy 3. Chronic portal hypertension	T	Units are in CC's Criteria updated April 11, 2002
Cancidas (caspofungin acetate)	18 and older	invasive aspergillosis infection	Patient must have failed on amphotercin B and itraconazole (Sporanox®) or have documented lab culture showing aspergillosis not sensitive to amphoterican B or itraconazole, and patient does not have any contraindications for the use of this product. Cancidas is not recommended for patients using cyclosporin or other immosuppressives.	W	PA duration: 3 months Utah MAC is $288.00 as of July 2001, One loading dose of a 70mg vial is allowed, then one 50mg vial per day maximum. 1 Unit = 1 vial Criteria effective October 1, 2001.
Flolan (epoprostenol na; prostayclin; PGI2; PGX)		Primary Pulmonary Hypertension	Prior authorization must be obtained by physician. 1. Covered only for patients with documented Primary Pulmonary Hypertension (ICD.9 = 416.0) 2. If the patent has a history of substance abuse, the patient must successfully complete a substance abuse rehabilitation program immediately before being placed on epoprostenol or must have documented abstinence (urine or blood test) for a period of at least six months. (Repeat on PA renewal)	W	Six month approval. Only authorize for specific daily amount prescribed by physician, rounded up nearest ampule size. 0.5mg amp= 500,000ng 1.5mg amp =1.500,000ng Criteria effective October 1, 2001.

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Ritalin / Methylphenidate	0 - 5 yrs.				Not a benefit for children from birth through age 5.
Ritalin / Methylphenidate	6 - 18 yrs.	❶ Attention Deficit Disorder ❷ Narcolepsy			
Ritalin / Methylphenidate	19 and older	❶ Narcolepsy ❷ Major or Atypical Depression ❸ Organic Brain Disorder includes but is not limited to: a. Congenital, such as cerebral palsy b. Infectious, such as encephalitis c. Traumatic, such as closed head injury d. Metabolic, such as diabetes ❹ Mental Retardation: a. if the patient exhibits injurious behavior b. is hyperactive c. has both diagnoses. *continued on next page*	❷ Medical necessity must be established. ❸ Provider must document the nature of the mental disorder and why methylphenidate is medically necessary. Documentation includes current evaluation, medical history, physical exam and history of treatment including effective and ineffective therapies given.		

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Ritalin / Methylphenidate	19 and older	*cont. from previous page* ❺ Attention Deficit Disorder	Ritalin / Methylphenidate for the diagnosis of Attention Deficit Disorder (ADD and ADHD) for patients age 19 and older requires written prior authorization. Criteria for approval are listed below: 1. If the patient has previously accessed Utah Medicaid for treatment of ADD with these medications, and the continuous use of treatment and drug is identified on the Utah Claims Payment History, prior authorization may be approved for one year without further testing. 2. Patients who come from out-of-state or whose medication has been paid by another source and who (1) have complete documentation required by Medicaid, including documentation of testing with an approved scale, and (2) have continuous use of medication may be approved for one year without further testing or psychiatric evaluation. 3. Patients who have no records of testing or previous use, or who have had a lapse in treatment for ADD from childhood and now present with symptoms of ADD as an adult, must have a diagnosis of ADD by one of the following methods: A. The Wender Utah Rating Scale with a score of 46 or greater. A copy of this scale may be obtained by contacting Medicaid Information; or B. The Conner test scale; or C. A level 2 psychiatric evaluation by a psychiatrist or a psychologist which results in a diagnosis of ADD; or D. Other validated testing which has been approved by the Department of Health and the Drug Utilization Review Board.	W	❺ Attention Deficit Disorder: Any of the following contraindications preclude payment for Ritalin for adults with ADD: Antisocial Personality Disorder. Schizotypal personality disorder or traits. Borderline personality disorder or traits. Active substance abuse or dependence. Reauthorization will be based on data supplied by the provider to validate improvement of function of the patient.

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Amphetamines	0 - 2 years				Not a benefit for ages 0 through 2 years.
Amphetamines	3 - 18 years	❶ Attention Deficit Disorder (ADD) ❷ Narcolepsy	Prescribers must hand write a correct ICD-9 code on all Medicaid pediatric prescriptions for amphetamines such as Adderall®, Dexedrine®, and Desoxyn®. The accepted ICD-9 codes are for the hyperkinetic syndrome of pediatrics. Telephoning the code to a pharmacy after the fact is not acceptable.		Criteria effective August 1, 1999
Amphetamines	19 and older	❶ Narcolepsy ❷ Traumatic brain injury ❸ Treatment resistant depression ❹ Attention Deficit Disorder (ADD and ADHD)	Amphetamines for patients age 19 and older require written prior authorization. 1. PA criteria for the diagnosis of Narcolepsy, Traumatic brain injury, or Treatment resistant depression are: A. History and physical report; B. Medical need must be documented; C. Documentation of failed treatments or medications used to treat diagnosis of treatment resistant depression. 2. PA criteria for the diagnosis of Attention Deficit Disorder (ADD and ADHD) are: A. If the patient has previously accessed Utah Medicaid for treatment of ADD with these medications, and the continuous use of treatment and drug is identified on the Utah Claims Payment History, prior authorization may be approved for one year without further testing. B. Patients who come from out-of-state or whose medication has been paid by another source and who (1) have complete documentation required by Medicaid, including documentation of testing with an approved scale, and (2) have continuous use of medication may be approved for one year without further testing or psychiatric evaluation. C. Patients who have no records of testing or previous use, or who have had a lapse in treatment for ADD from childhood and now present with symptoms of ADD as an adult, must be diagnosed with ADD by one of the following methods:	W	For all diagnoses, a maximum of one year's prior approval may be granted. Extension or renewal will require proof of improvement with data/documentation supplied by the provider and physicians. For ❹ Attention Deficit Disorder, any of the following contraindications preclude payment for Ritalin for adults: – Antisocial Personality Disorder – Schizophrenia – Schizo-affective disorder – Schizotypal personality disorder or traits – Borderline personality disorder or traits – Active substance abuse or dependence

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
			– The Wender Utah Rating Scale with a score of 46 or greater. A copy of this scale may be obtained by contacting Medicaid Information; or – The Conner test scale; or – A level 2 psychiatric evaluation by a psychiatrist or a psychologist which results in a diagnosis of ADD; or – Other validated testing, which has been approved by the Department of Health and the Drug Utilization Review Board.		
Lufyllin (dyphylline)			Lufyllin (dyphylline) requires written prior authorization (PA) . Physician must obtain PA. Criteria are as follows: 1. Failure with two or more other agents of the xanthine therapeutic class a. Documentation in writing b. Blood level of generic failures c. Description of failure 2. Failure with generic equivalent of Lufyllin elixir, Lufyllin-GG elixir, or Lufyllin-EPG elixir formulations a. Documentation in writing b. Blood level of generic failures c. Description of failure	W	Therapeutic class: A1B, Xanthines: GGN.SEQNO: 000130, 000133, 000132 combinations: dyphylline/ephedrine/gg/penobarb: 000164, 000165 dyphylline/gg: 000170, 000168 Criteria effective October 1, 1996

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Growth hormones for children Group 1 - somatrem Protropin -somatropin Humatrope Nutropin Group 2 -somatropin Humatrope Nutropin	0 - 18 years	Group 1: documented lack of adequate endogenous growth hormone secretion. Group 2: documented chronic renal insufficiency up to the time of renal transplantation.	Growth hormones for children to treat growth failure require written prior authorization (PA). A copy of the physician's prescription must be submitted with request for PA . Prescriptions must be written by prescriber. PA can be given for 12 months, after which the PA must be renewed. 1. The patient must be fifteen years of age or younger to initiate growth hormone therapy. Eligibility for sustained treatment is covered through age eighteen. 2. The patient must have a height stature less than the 5th percentile on the PHYSICAL GROWTH NCHS (National Center for Health Statistics) PERCENTILES chart for correct age and sex. Charts are an attachment to the Drug Criteria and Limits List. 3. The patient's growth rate must be documented in centimeters for at least six months immediately before initiation of growth hormone treatment. 4. The patient must be under care of an endocrinologist or have extensive endocrinologist consult. 5. The patient must have either a documented endogenous growth hormone secretion of < 10mcg/L after provocative stimulation; or the patient must have growth failure associated with documented chronic renal insufficiency up to the time of renal transplantation. Prior authorization may be renewed if the patient meets the PA criteria AND the yearly growth rate exceeds the untreated growth rate by 2 centimeters a year. [treated growth rate minus untreated growth rate > 2 cm.] With the request for renewal, submit: 1. Patient's weight in kilograms, height in centimeters, and weekly dose in mg. per kilometer for the preceding three calendar quarters to document growth. 2. Copies of all prescriptions since the last date of prior authorization.	W	Group 1: Weekly dose cannot exceed .3mg per kilogram body weight. Group 2: Weekly dose cannot exceed .35mg per kilogram body weight. Total vials of growth hormone required are figured by dividing total milligrams of growth hormone required for 12 months by size of vials (mg/vial) used. Formula: Multiply number of mgs. per dose by number of doses per week = mgs/week. Multiply mgs/week by 52 weeks = total mgs/year. Divide mgs/year by number of mgs. per vial = number of vials for 12 month period. NOTE: Reconstituted vials are stable under refrigeration for: - somatropin: 14 days - protropin: 7 days

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	P A	COMMENTS
Growth hormones for adults Group 1 - somatrem Protropin -somatropin Humatrope Nutropin Group 2 -somatropin Humatrope Nutropin Growth hormones for adults, *continued*	Over 18 years of age	AIDs wasting indication	Growth hormones for adults require written prior authorization (PA). Pharmacy obtains written prior approval. Physician must provide requested attachments before the PA must be renewed. 1. Patient must consistently be participating correctly in HAART (highly active antiretroviral therapies. One time purchase of HAART regimen not sufficient. Submit copy of patient records documenting HAART regimen. 2. Body composition and weight loss must be established by Bioelectrical Impedance Analysis (BIA), or patient must have documented unintentional weight loss of at least 10% of baseline premorbid weight or body mass index of < 20kg/m^2. Baseline weight_____ Current weight_____ Height_____ Rule out causes of weight loss including hypogonadism, opportunistic infections, diarrhea, inadequate nutrition intake, malabsorption, and thyroid abnormalities. 3. Rule out hypotestosterone levels since hypogonadism is common among HIV infected individuals. If testosterone levels < 500 ng/dL (in men), try testosterone. 4. Prescribe resistance exercise program. 5. If testosterone replacement therapy is inadequate, add oxandrolone. (Dosing range is 2.5-15mg per day.) Oxandrolone is available only for AIDS wasting syndrom via telephone prior approval. A. Trial period on Oxandron® (oxandrolone) 2.5mg-20mg/day 60 day period. If effective, remain on Oxandron. B. Obtain patient weight before and after Oxandron trial. 6. Prior approval for human growth hormone: If no other causes of weight loss are found, and there is a treatment failure on anabolic steroid therapy, human growth hormone (GH) may be used under the following conditions: A. Patient must be able to maintain 100% of daily nutritional intake. B. For patients receiving enteral or parental nutrition, the patient must be weight stable for two (2) months. C. Patient must not have an untreated or suspected systemic infection or persistent fever $\geq$ 101° F during the 30 days prior to evaluation of weight loss. Continued on next page ➔ D. Patient must not have any signs or	W	The American Association of clinical Endocrinologists (AACE) recommended dosage is: For patients < 35 years of age - 1.75mg per day For patients > 35 years of age - 0.875mg per day Total vials of growth hormone required are figured by dividing total milligrams of growth hormone required for 12 months by size of vials (mg/vial) used. Formula: Multiply number of mgs. per dose by number of doses per week = mgs/week. Multiply mgs/week by 52 weeks = total mgs/year. Divide mgs/year by number of mgs. per vial = number of vials for 12 month period. Reconstituted vials are stable under refrigeration for: - somatropin: 14 days - protropin: 7 days Dose Guidelines for Serostim from Package Insert are: Weight Range Dose >55 kg 6mg SC daily 45-55 kg 5mg SC daily 35-45 kg 4mg SC daily < 35 kg 0.1mg/kg SC daily Measurement of growth hormone is an added cost with no clear benefit. Overt GH deficiency does not appear to be common in HIV-positive individuals. However, AIDS-

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	P A	COMMENTS
			symptoms of gastrointestinal malabsorption or blockage unless on total parenteral nutrition. E. Patient must not have active malignancy, except for Kaposi's sarcoma (KS). 7. If the criteria in item 6 are met, then the initial approval period will be twenty one (21) days at AACE recommendations; fourteen (14) days at package insert dosing. Documentation must show weight stabilization by the end of the initial period, or second approval will not be granted. (Stabilization = no weight loss while on growth hormone) Patient's pre-GH weight: _____ Weight after 14 days : _____ 8. After the initial trial dosage period, a second approval must be obtained to continue therapy for an additional four (4) weeks therapy. A. Continued weight loss precludes additional approvals. B. If patient's weight increases during the additional four (4) week therapy, approval may be obtained for an additional six (6) weeks therapy. 9. Medicaid will approve therapy only to a maximum of twelve (12) weeks per any six month episode.		wasting has linked to a GH-resistant state. Criteria effective October 1, 1999

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	P A	COMMENTS
Darvon®, Darvocet N®		History must show pain management failure of at least one other type of analgesics.	Darvon®, Darvocet N® require written prior authorization. The requirement applies to the brand names only. Generic forms of propoxyhene do not require prior authorization. The physician or prescriber must supply to the pharmacy the following. 1. A copy of the physician's prescription for Darvon or Darvocet-N must be submitted with the request for prior authorization (P A). 2. The prescriber must hand-write on prescription “name brand medically necessary”. NOTE: Patient preference is not considered a medical necessity. 3. Physician must supply copy of patient record/history showing reason for medical necessity. 4. History must show pain management failure of at least one other type of analgesics. 5. Documentation must show trial period on generic with documentation of failure and why the generic version failed. PA can be given for six months, after which the PA must be renewed.	W	The quantity limit is 180 tablets per prescription. The prescription limit is twelve prescriptions in six months.

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
5-HT^3 Receptor Antagonists **Zofran® (ondansetron HCL)** Anzemet® (dolasetron mesylate) Kytril® (ondansetron HCL)			The pharmacist must make the request for prior approval.	T	PA for one year maximum units:
		❶ Nausea or vomiting related to oncology treatment (chemotherapy or radiotherapy) or pregnancy	❶ Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetigenic cancer chemotherapy; Prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen		❶ Oncology -360 tablets max ❷ Prevention of post/op n/v - 30 tablets max. ❸ morning sickness - 90 days: 90 tablets max. at 1 qd
		❷ Prevention of postoperative nausea and/or vomiting	❷ Prevention of postoperative nausea and/or vomiting		
		❸ Pregnancy related nausea or vomiting (morning sickness):	❸ Pregnancy related nausea or vomiting (morning sickness): The prescriber must provide documentation to the pharmacist from the patient's medical record that at least one of the following conditions has been met: A. Duration of onset of nausea/vomiting has exceeded one week, and patient has failed to respond to other medications including at least a trial on each of pyridoxine and phenothiazines and benzodiazepines. B. Patient has received I.V. rehydration with imminent hospital admission if vomiting can not otherwise be controlled. Approval may be given for up to ninety (90) days. Maximum units are 90 tablets (30 per month).		Criteria effective July 1, 2001.

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Enbrel ® (etanercept)	minimum age 4 years	moderate to severe rheumatoid arthritis	Etanercept requires written prior authorization. The patient's physician must obtain authorization from Medicaid. Documentation can be FAXed or mailed. There are ten conditions for coverage: 1. The patient is at least 4 years of age. 2. Patient has rheumatoid arthritis 3. Patient has documented history of treatment failure, incomplete response or intolerance to: a. Methotrexate b. At least one other DMARD or second line drug (azathioprine, gold, sulphasalazine, leflunomide, penicillamine, hydroxychloroquine, etc). 4. Patient does not have an immunosupressive condition 5. Patient does not have an active bacterial or viral infection 6. Patient does not have a malignancy 7. Patient has had a documented rheumatologist consultation within the last sixty days 8. Initial prior approval is for 12 weeks - 24 kits maximum date number of kits 9. Subsequent PA for 12 months, 112 kits maximum, if patient has at least 20% improvement in four of the following six parameters: tender joint count, swollen joint count; patient global assessment of disease activity; physician global assessment; pain; acute phase reactants. 10. Etanercept may not be given with other biologic agents (such as interferon, etc) or experimental medication combinations.	W	Enbrel (etanercept) is the first biologic response modifier approved for the treatment of patients with moderate to severe rheumatoid arthritis. Enbrel acts by binding tumor necrosis factor, one of the dominate cytokines in the inflammatory cascade. Enbrel is given SQ, twice weekly. Cost at EAC (AWP-12%) is $121.00 or ~$ 1,129.33 per month. AWP = 155.70/kit 4/17/02 Criteria updated April 11, 2002

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Regranex (becaplermin) 0.01% topical gel			Regranex (becaplermin) 0.01% topical gel requires written prior approval. Pharmacy obtains the PA. Physician must provide requested attachments. Regranex has been approved by the FDA for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. Regranex is to be used as an adjunct to, and not a substitute for good ulcer care practices including initial sharp debridement, pressure relief and infection control. The efficacy of Regranex Gel for the treatment of diabetic neuropathic ulcer that do not extend through the dermis into subcutaneous tissue (State 1 or II, IAET [International Association of Enterostomal Therapy] staging classification) or ischemic diabetic ulcers has not been evaluated. Criteria for PA are: 1. Rule out venous ulcers and/or arterial ulcers. 2. Patient must be diabetic, either Type I or Type II. Existing prescription for insulin or oral hypoglycemics: Y/N _____ Not covered for diabetic ulcer above ankle. 3. Patient must have stage III or IV diabetic foot or ankle ulcer as defined in the International Association of Enterostomal Therapy guide to chronic wound staging, 1989. These states included ulcers into the subcutaneous tissues. 4. The first prior approval is for 8 weeks only. A 30% reduction in ulcer size must be achieved before a second prior is obtained. 5. Size and shape of ulcer must be documented. Length:_____ width: _____ Draw shape: 6. Any given ulcer is limited to treatment of a maximum of 60 grams of Regranex. 7. The subcutaneous diabetic foot ulcer may not exceed 3 cm in diameter or total surface are of 9.42 cm^2. Size and shape of ulcer must be documented. Length:_____ width: _____ Draw shape: Continued on next page ➔	W	Regranex supplied as single 15gm tube. AWP as of October 1999 is $396.54. Criteria effective October 1, 1999

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Regranex (becaplermin) 0.01% topical gel, continued			Continued from previous page 8. Total contact casting is an available method of treatment and must be considered and rejected before Regranex is to be considered. 9. The second prior approval is for 8 weeks only. Size and shape of ulcer must be documented. Length:_____ width: _____ Draw shape: 10. Any given ulcer is limited to treatment of a maximum of 60 grams of Regranex.		

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Panretin® Topical Gel 0.1% (9-cis-retinoic acid) (alitretinoin)		Kaposi's Sarcoma (KS)	Panretin® Topical Gel 0.1% (9-cis-retinoic acid) (alitretinoin) requires written prior approval. Pharmacy obtains written prior approval. Physician must provide requested attachments. 9-cis-retinoic acid has been approved for Kaposi's Sarcoma (KS), a frequently encountered malignancy in HIV-positive patients. 9-cis-retinoic acid is an isomer of trans-retinoic acid (tretinoin) or Retin-A®. terms: KS Kaposi's Sarcoma PRA partial response area PRH partial response height 1. Panretin is not indicated when systemic anti-KS therapy is required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement.) Note. Board approved Retin-A use (via PA) for KS treatment pre-Panretin. 2. Diagnosis of cutaneous lesions caused by Kaposi's Sarcoma. Primary number of KS lesions:_____ Estimated total square centimeters:_____ 3. 60 day trial period on 0.1% Retin-A gel - by prior approval. 4. If client sustains an improvement of >25% or more from base line (both PRA and PRH){see table 1}, remain on Retin-A gel. Primary number of KS lesions:_____ Estimated total square centimeters:_____ 5. If improvement < 25%, then 0.1% Panretin Gel* Panretin may be tried for a thirty (30) day trial period. Patient must sustain partial response defined as a 25% or more improvement from baseline for PRA and 25% or more improvement from baseline of PRH before additional coverage is approved. Single 60 gm tube of Panretin gel is approved. Number of KS lesions :_____ Estimated total square centimeters:_____ 6. A sixty (60) day treatment period with Panretin Gel** may be approved. Patient must sustain 50% or more improvement from baseline. Four 60 gm tubes cumulative maximum per year. Continued on next page ➔	W	How supplied: Panretin 0.1% gel Description: single 60gm tube AWP: $2,439.31 Generic name: 9-cis-retinoic acid (1gm = 1 unit) *(4) 60gm tubes cumulative maximum per year. (240gm/units/per-year) *Each tube requires a new prescription from the physician. Criteria effective October 1, 1999.

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Panretin® Topical Gel 0.1% (9-cis-retinoic acid) (alitretinoin)			Continued from previous page 7. Continued use of Panretin–State of continued improvement		

Table 1. ACTG Response Criteria as Applied for Topical Therapy+

Assessment of lesions is limited to only the cutaneous lesions treated. Each lesion assessed for height and diameter. The response evaluation of each KS index lesion will be classified according to the following system:	
Complete Response (CR)	Decrease in lesion area to zero and biopsy documenting absence of KS cells
Clinical complete Response (CCR)	Decrease in lesion area to zero
Partial Response area (PRA)	Decrease in lesion area by 50% or more from baseline without concurrent increase in height of lesion from flat (macular) at baseline to raised (plaque-like or nodular)
Partial Response Height (PRH)	complete flattening of a lesion raised at baseline (decrease in height from nodular or plaque-like to macular) without concurrent increase in lesion area by 25% or more from baseline
Stable Disease (SD)	Lesion does not meet evaluation criteria for CR, CCR, PR, or PD
Progressive Disease (PD)	Increase in lesion area by 25% or more from baseline area, or an increase in height from flat (macular) at baseline to raised (Plaque-like or nodular)

+table 1 supplied by Ligand Pharmaceuticals

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Adagen (Pegademase bovine) 375u/vial 250u/ml 1.5ml/vial		ADA adenosine deaminase deficiency	Adagen (Pegademase bovine) requires written prior authorization (PA). The pharmacist must obtain the PA. Criteria are: 1. Covered only for patients with documented ADA deficiency. 2. Documentation required: – Copy of prescription from physician – Name, address, phone number of prescribing physician – Name, address and phone number of pharmacy 3. Dose must be delivered in a pre-filled syringe for exact dose. 4. If there is a change in dose, a new prior authorization is required. Medicaid must be notified in writing. Send copy of the new prescription. PA is valid for six months.	W	Only authorize for specific amount of ml's prescribed by physician. Example: Number of ml's/dose, times number of doses per week, times number of weeks in the six months. (May have to convert Units) Usual Dose: 20u.kg/wk Criteria effective March 1, 2000
Cerezyme Imiglyceraze 200u vial 400u vial		Gaucher's Disease	Cerezyme Imiglyceraze requires written prior authorization (PA). The pharmacist must obtain the PA. Criteria are: 1. Covered only for patients with documented Goucher's Disease. 2. Documentation required: – Copy of prescription from physician – Name, address, phone number of prescribing physician – Name, address and phone number of pharmacy 3. If there is a change in dose, a new prior authorization is required. Medicaid must be notified in writing. Send copy of the new prescription. PA is valid for six months.	W	Only authorize for specific amount prescribed by physician. Criteria effective March 1, 2000

INHALERS	LIMIT IN ANY 30 DAY PERIOD				
Effective April 1, 2002, the cumulative number of inhalers in any 30-day period is limited for a Medicaid client. The limit is set by class (excepting Foradil and Serevent which are limited by NDC number). This means the highest number in any one class is the maximum. When there are more than two sizes or strengths for a given product, the limit is based on the largest size or strength. There are two groups of inhalers: oral and nasal. For each group, the limits are stated below.					
Inhaler Class	**Generic Name**	**Brand Name**	**Product Size**	**Doses per Inhaler**	**Maximum No. In 30 Days**
Nasal Anti-inflammatory Inhalers	beclomethasone	Beconase	6.7	80	2
	beclomethasone	Beconase	16.8	200	2
	beclomethasone	beconase AQ	25	200	2
	fluticasone	Flonase	16	120	1
	trimcinolone	Nasacort	10	100	3
	triamcinolone	Nasacort AQ	16.5	120	2
	flunisolide	Nasalide	25	200	3
	flunisolide	Nasarel	25	200	3
	mometasone	Nasonex	17	120	1
	budesonide	Rhinocort	7	200	2
	budesonide	Rhinocort AQUA	8.4	120	2
	beclomethasone	Vancenase	16.8	200	2
	beclomethasone	Vancenase AQ	25	120	1
ORAL INHALERS	**Generic Name**	**Brand Name**	**Product Size**	**Doses per Inhaler**	**Maximum No. In 30 Days**
Beta 2 agonists and Sympathomimetics	Albuterol	generic	17 gm	200	4
		Proventil	17 gm	200	4
		Proventil HFA	6.7 gm	200	4
		Ventolin	6.8 gm	80	4
			17 gm	200	4
		Ventolin Rotacaps		100	4
	Bitolterol	Tornalate	16.4 gm	300	3
	Formoterol	Foradil		18	3
				60	3
	Metaproterenol	Alupent	14 gm	200	3
	Pirbuterol	Maxair	25.6 gm	300	3
		Maxair autohaler	2.8 gm	80	2
			14 gm	400	2
	Salmeterol	Serevent	6.5 gm	60	2
			13 gm	120	2
		Serevent Diskus		60	2
	Terbutaline	Brethaire	10.5 gm	300	3

Inhaler Class	Generic Name	Brand Name	Product Size	Doses per Inhaler	Maximum No. In 30 Days
Anticholinergics	Ipratropium	Atrovent	14 gm	200	3
	Ipratropium / Albuterol	Combivent	14.7 gm	200	3
Corticosteroids	Beclomethasone	Beclovent	6.7 gm	80	4
			16.8 gm	200	4
		Qvar	7.3 gm	100	4
				100	4
	Budesonide	Pulmicort Turbuhaler		200	3
	Flunisolide	AeroBid, AeroBid-M	7 gm	100	3
	Fluticasone MDI	Flovent 44 mcg, 110 mcg, and 220 mcg	7.9 gm	60	4
				60	4
				60	4
			13 gm	120	4
				120	4
				120	4
	Fluticasone DPI	Flovent Rotadisk 50 mcg, 100 mcg, and 250 mcg		60	3
				60	3
				60	3
	Triamcinolone MDI	Azmacort	20 gm	240	3
	Fluticasone / Salmeterol DPI	Advair diskus 100/50		60	2
		Advair diskus 250/50		60	2
		Advair diskus 500/50		60	2
Mast cell stabilizers	Cromolyn MDI	Intal	8.1 gm	112	3
			14.2 gm	200	3
	Nedocromil MDI	Tilade	16.2 gm	112	3

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Orlistat (Xenical) 120mg capsules		hypercholesterolaemia	Orlistat (Xenical) requires written prior authorization (PA). Criteria are: 1. Covered only as an adjunct to a treatment regimen of diet, exercise, behavior modification, and one or more antihyperlipidemic medications (specifically LDL lowering agent(s) – niacin, bile acid sequestrants, and/or HMG Co A reductase inhibitors). 2. Patient must have experienced treatment failure (defined as not being at NCEP goal for LDL cholesterol based on patient risk factors * $) after three months of therapy at maximally tolerated doses of antihyperlipidemic agents (niacin, bile acid sequestrants, and/or HMG Co A reductase inhibitors). * LDL goals by NCEP criteria: No CHD + < 2 risk factors ➜ goal is LDL < 160 No CHD + ≥ 2 risk factors ➜ goal is LDL < 130 CHD, ASVD or diabetes mellitus ➜ goal is LDL ≤ 100 $ Cardiac Risk Factors as defined by NCEP guidelines: – Male ≥ 45, female ≥ 55 – Family history of premature CHD (first degree relative, male < 55, women < 65 with MI or sudden cardiac death) – Current cigarette smoking – Hypertension – HDL < 35 – Diabetes – HDL ≥ 60 is a negative risk factor 3. Orlistat must be used in addition to maximally tolerated doses of niacin or bile acid sequestrants, and/or HMG Co A reductase inhibitors; diet, exercise and behavior modification. 4. First time period for authorization is 90 days, during which patient must achieve a reduction in LDL cholesterol of 5% from baseline (immediately prior to starting Orlistat) 5. Additional prior authorizations will be in six month increments. 6. Initial LDL levels must be documented, both pre initiation/during therapy of niacin, bile acid sequestrants, and/or HMG Co A reductase inhibitors; and pre orlistat therapy.	W	Recommended dose: No more than one capsule three times a day. Criteria effective July 1, 2000.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
			7. Orlistat will not be covered for use for weight loss or for the reduction of isolated elevated triglyceride levels. **Check List for Orlistat Prior Authorization:** 1. Patient name: _____ 2. Prescriber: _____ 3. Patient weight: _____ (Patient weight must be recorded for each PA time span.) 4. Height: _____ 5. Cardiac risk factors (circle if patient has) – Male ≥ 45, female ≥ – Family history of premature CHD (first degree relative, male < 55, women < 65 with MI or sudden cardiac death) – Current cigarette smoking – Hypertension – HDL < 35 – Diabetes – HDL ≥ 60 is a negative risk factor 6. Goal LDL for patient (by NCEP guidelines) _____ 7. LDL prior to all drug therapy: _____ 8. LDL after maximally tolerated niacin, bile acid sequestrants, and/or HMG Co A reductase inhibitors: _____ (This should be the same as the pre-Orlistat LDL.) 9. Current antihyperlipidemic regimen: _____ 10. LDL after 90 days of orlistat: _____ (For reapproval, this must be at least 5% lower than value in number 6.)		

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Oseltamivir phosphate (Tamiflu7) 75mg Capsule	> 17 yrs.	1. influenza A influenza B 2. prophylaxis	1. <u>Diagnosis of influenza A or influenza B</u> Oseltamivir phosphate (Tamiflu7) requires prior authorization (PA), which may be requested by telephone. Covered only for patient at high risk from diagnosed and documented disease states or immunodeficient patient. The term immunodeficient includes: HIV/AIDS or other diseases that affect the immune system; long-term radiation treatment; long-term treatment with drugs such as steroids; oncology agents; immuno-suppressive agents. Documentation must be provided that demonstrates that one other household member or residential member currently has documented influenza A or Influenza B. (Verbal from doctors office)(Lab work in a Nursing Home) 2. <u>Prophylaxis</u> Covered only for patients at high risk from diagnosed and documented disease states of: a. severe cardiopulmonary conditions b. immunocompromised patients c. fragility due to extreme age (greater than 65 years).	T	<u>Diagnosis of influenza A or influenza B</u> Limit: Tamiflu is dosed at 75mg capsules twice daily for 5 days. Therefore, the limit is ten capsules or tablets per year. The FDA has not cleared Tamiflu for children ages 17 and younger. <u>Prophylaxis</u> 7 day treatment for prophylaxis. Limit of 14 tablets. Criteria updated July 1, 2001
Zanamivir (Relenza) 5mg amp	> 13 yrs.	influenza A influenza B	Zanamivir (Relenza) requires prior authorization (PA), which may be requested by telephone. Covered only for patient at high risk from diagnosed and documented disease states or immunodeficient patient. The term immunodeficient@ includes: HIV/AIDS or other diseases that affect the immune system; long-term radiation treatment; long-term treatment with drugs such as steroids; oncology agents; immuno- suppressive agents.	T	Dose: 10mg bid delivered via oral inhaler for five days Limit: one box of 20 5mg amps per year. Criteria effective April 1, 2000.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Low Molecular Weight Heparins (LMWH): ❶ dalteparin sodium (Fragmin) ❷ tinazajparin Na (Innohep) ❸ enoxaparin Na (Lovenox)	> 17 yrs.		❶ dalteparin sodium (Fragmin) A. Unstable angina/Non-Q-wave MI: For the prophylaxis of ischemic complications in unstable angina and non-Q-wave MI in patients on concurrent aspirin therapy. B. Deep vein thrombosis (DVT) prophylaxis: For prophylaxis of DVT, which may lead to pulmonary embolism (PE), in patients undergoing hip replacement surgery or in patients undergoing abdominal surgery who are at risk for thromboembolic complications. Patients at risk include those who are > 40 years of age, obese, undergoing surgery under general anesthesia lasting > 30 minutes, or who have additional risk factors such as malignancy or a history of DVT or PE. ❷ tinazajparin Na (Innohep) Deep vein thrombosis (DVT): Treatment of acute symptomatic DVT with or without pulmonary embolism (PE) when administered in conjunction with warfarin sodium. ❸ enoxaparin Na (Lovenox) Deep vein thrombosis (DVT) prophylaxis: For prevention of DVT, which may lead to pulmonary embolism (PE) in patients undergoing hip replacement surgery (during and following hospitalization), knee replacement surgery, or abdominal surgery who are at risk for thromboembolic complications. A. Patients at risk include those who are > 40 years of age, obese, undergoing surgery under general anesthesia lasting > 30 minutes, or who have additional risk factors such as malignancy or a history of DVT or PE. B. DVT/PE treatment: In conjunction with warfarin sodium for inpatient treatment of acute DVT with and without PE or outpatient treatment of acute DVT without PE. C. Unstable angina/Non-Q-wave MI: For the prevention of ischemic complications of unstable angina and non-Q-wave MI when co-administered with aspirin. D. Approved for two days pre-op for clients who must stop Coumadin therapy prior to surgery. E. Approved for up to five days post-op for clients starting Coumadin therapy.	T	Criteria updated July 1, 2002

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
			F. Use during pregnancy (written prior) G. Unfractionated heparin is recommended if the time period of the pregnancy is not more than 6 months . Heparin induced thrombocytopenia and/or osteopenia usually occur when unfractionated heparin is used longer than six months. 1. PROPHYLAXIS - Enoxaparin is indicated for thromboembolism prophylaxis during pregnancy when the patient has: a. Past history of DVT/PE, or known hypercoagulability. b. Failed previous treatments with subcutaneous heparin (due to allergy). c. Prophylaxis period that will last through entire pregnancy (or greater or equal to 6 months). d. Dose is 1mg/kg BID (maximum). 2. ACTIVE TREATMENT OF DVT - Enoxaparin is indicated for thromboembolism treatment during pregnancy when: a. Patient has clinical evidence of a DVT or PE. b. Treatment period will consist of a period greater or equal to 6 months. c. The patient has an allergy to unfractionated heparin. d. The initial dose of enoxaparin during pregnancy is 1mg/kg BID. (If the patient is being treated for a thromboembolism, the dose may be titrated upwards until heparin anti-Xa levels fall between 0.4-0.7 U/ml.) There is no clinical evidence that dosing more frequently than BID improves treatment efficacy. Dosage should be individualized to keep the anti-Xa levels in the appropriate range.		

DRUG	AGE	DIAGNOSIS	CRITERIA & INSTRUCTIONS	PA	COMMENTS
Zyban or Nicotine Replacement Therapy		pregnant woman who uses tobacco	Nicotine Replacement Therapy requires prior authorization (PA), which may be requested by telephone. The pharmacist must obtain the required prior approval. Criteria are: 1. A physician must write a prescription for participation in the Medicaid Smoking Cessation Program (SCP). The prescriber should include the estimated due date on the prescription. 2. If the prescriber has not provided the due date, the pharmacist may obtain it from the patient. 3. Women who qualify for the Smoking Cessation Program are covered only for a twelve week period per any given pregnancy. The twelve week period may include two weeks past the estimated due date. 4. Limits on products are listed in the next column. 5. Therapeutic duplication is not recommended. However, if requested, it may be approved.	T	Limits on products are: – Topical products (patches) are limited to one patch per day. (30 per month, 120 per 3-month period) – Nicotine gum products are limited to 20 doses per day. (600 per month, 1800 per 3-month period) – Nicotine inhaler cartridges are limited to no more than 16 per day. (480 per month, 1440 per 3-month period) – Nicotine nasal spray is limited to no more than 15 bottles per month. (one bottle = 10cc) (45 per 3-month period) – Zyban (bupropion) is limited to no more than two tablets per day. (60 per month, 180 per 3-month period) Criteria effective January 1, 2001.
Zyban	18 and older	Medicaid client who uses tobacco	The pharmacist must obtain the required prior approval. Criteria are: 1. A physician must write a prescription for use of Zyban. 2. Coverage is only for a twelve week period per year.	T	Zyban (bupropion) is limited to no more than two tablets per day. (60 per month, 180 per 3-month period) Criteria effective April 1, 2002.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Proton Pump Inhibitors (PPIs)		GERD symptoms and/or bleeding peptic ulcer disease	1. Proton pump inhibitors (PPIs) are restricted to one dose daily. The point-of-sale's 30 day cumulative limit logic will be used to limit PPIs to thirty doses in any 30 day time period effective July 1, 2001. The 30 unit limit is for all PPIs in any combination and any oral strength (same logic as used with the narcotic/APAP limits). 2. Twice daily dosing is allowed with a prior approval (PA) for presenting acute states of GERD, ulcers, or hypersecretory conditions for up to sixty days. Physicians (prescribers) are responsible for providing the pharmacy with written documentation supporting any of these three conditions. a. The Medicaid prior approval unit will issue a PA number to select pharmacy for a total of time period of sixty days and 120 doses. b. PA unit will contact Claims Management unit by e-mail and get an override for the PA. The e-mail is to be saved which creates the requisite audit trial. 3. Any requests for PPIs with dosing outside of the above limits will require the patient's physician to petition the DUR Board.	W	Criteria effective July 1, 2002
Lovenox		❶ Post Surgical Use ❷ Unstable angina/Non-Q-wave MI ❸ Deep vein thrombosis (DVT) prophylaxis ❹ DVT/PE treatment	Limit of twenty units. ❷ For the prophylaxis of ischemic complications in unstable Angina and non-Q-wave Mi in patients on concurrent aspirin therapy. ❸ For prophyllaxis of DVT, which may lead to pulmonary embolism (PE), in patients undergoing hip replacement surgery or in patients undergoing abdominal surgery who are at risk for thomboembolic complications. Patients at risk include those who are > 40 years of age, obese, undergoing surgery under general anesthesia lasting > 30 minutes, or who have additional risk factors such as malignancy or a history of DVT or PE. ❹ In conjunction with warfarin sodium for inpatient treatment of acute DVT with and without PE or outpatient treatment of acute DVT without PE.	T	Covered for below the waist surgeries only.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Lovenox		❺ Prophylaxis for DVT/PE during pregnancy	❺ Criteria for use as prophylaxis during pregnancy: 1. Past history of DVT/PE, or known hypercoagulability and 2. Failed previous treatments with subcutaneous heparin (due to allergy). 3. The prophylaxis period that will last through entire pregnancy (or greater or equal to 6 months). 4. Dose is 1mg/kg BID.	W	Unfractionated heparin is recommended if the time period of the pregnancy is less than 6 months. Heparin induced thrombocytopenia and/or osteopenia usually occur when unfractionated heparin is used longer than six months. There is no clinical evidence that dosing more frequently than BID improves treatment efficacy. Dosage should be individualized to keep the anti-Xa levels in the appropriate range. Criteria updated July 1, 2001
		❻ Active treatment of DVT during pregnancy	❻ Criteria for use during pregnancy: 1. Patient has clinical evidence of a DVT or PE. 2. Treatment period will consist of a period greater or equal to 6 months. 3. The patient has an allergy to unfractionated heparin. 4. The initial dose of enoxaparin during pregnancy is 1mg/kg BID. (If the patient is being treated for a thromboembolism, the dose may be titrated upwards until heparin anti-Xa levels fall between 0.4-0.7 U/ml.)		

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Tracleer	>12	pulmonary arterial hypertension (PAH) in patients with WHO class III or IV symptoms (WHO = World Health Organization)	Physician obtains written prior approval. Six months' approval when following criteria are met: 1. Covered only for patients with documented class III or class IV pulmonary arterial hypertension. 2. Copy of prescription from physician. (copy to Medicaid) 3. Name, address, phone number of prescribing physician. (to Medicaid) 4. Name, address and phone number of pharmacy.	W	Females can not be capable of becoming pregnant Contraindicated for patients with moderate to severe liver impairment. Contraindicated for patients taking cyclosporine or glyburide. Dose: 62.5mg b.i.d. for 4 weeks, then increased to 125mg b.i.d. (Maximum) Medicaid Cost: 43.56/tablet (approximately $32,000/yr) Criteria effective April 8, 2002

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Anakinra (Kineret)	18 years and older	rheumatoid arthritis (ICD-9 codes 714.0; 714.3)	Physician gets prior approval. Criteria for use of anakinra (Kineret): Maximum dose: 100mg daily Documentation can be FAXed or mailed. 1. Patient has rheumatoid arthritis 2. Patient has documented history of treatment failure, incomplete response or intolerance to: a. Methotrexate b. At least one other DMARD or second line drug (azathioprine, gold, sulphasalazine, leflunomide, penicillamine, hydroxychloroquine, etc) and c. anakinra (Kineret), etanercept (Enbrel) and infliximab (Remicaid) are mutually exclusive. Patient can only be on one of these agents at a time. 3. Subsequent PA for 12 months - if patient has at least 20% improvement in four of the following six parameters: tender joint count, swollen joint count; patient global assessment of disease activity; physician global assessment; pain; acute phase reactants. 4. Anakinra may not be given with either etanercept (Enbrel) or infliximab (Remicaid). primary number of swollen joints _____ primary number of tender joints _____	W	Anakinra (Kineret) is a recombinant, nonglycosylated form of the human interleukin-1 receptor antagonists (IL-1Ra). Anakinra differs from native human IL-Ra in that is has the addition of a single methionine residue at its amino terminus. Anakinra blocks the biologic activity of IL-1 by competitevely inhibiting IL-1 binding to the interleukin-I type 1 receptor (IL-1RI), which is expresssed in a wide variety of tissues and organs. How supplied: 100mg/0.67ml prefilled syringe. no preservatives Dosage is 100mg qd. Cost for a 100mg dose is EAC (AWP-12%) is $41.25 The cost per month is: 41.25 x 88% (EAC) = $36.30/dose X 30 = ~$ 1,089 per month. AWP $61.57 per 100mg syringe (2/15/02) Criteria effective March 14, 2002.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Epoetin Alfa (Epogen, Procrit), Darbepoetin Alfa (Aranesp)		**Epoetin Alfa, Darbepoetin Alfa:** A. anemia associated with renal failure if patient is not on dialysis. B. anemia associated with chemo-therapy for non-myeloid malignancies where clients will be receiving chemotherapy for a minimum of two months. **Epoetin Alfa only** A. blood transfusions, allogenic and anemic surgery patients. (approve one time only) B. anemia associated with treatment with Zodovudine in HIV infection.	1. Due to the nature of these drugs, prescribing authority is limited to hematologists, oncologists, nephrologists, and infectious disease specialists or based upon a consult with one or these specialists. 2. Client's iron status should be assessed before epoetin therapy begins. The values for transferrin saturation should be >20% and for ferritin > 100ng/ml or the patient should be on appropriate concurrent iron therapy. Iron replacement therapy as appropriate. 3. The client should be evaluated for other causes of anemia, such as: a. Underlying infectious or inflammatory process b. Occult blood loss c. Underlying hematologic disorders d. Aluminum intoxication e. Osteitis fibrosa cystica f. Vitamin deficiencies - Folic acid or B12 (lab results required). 4. The client should not have an active gastrointestinal bleed or should be under treatment for the condition. 5. Client's hypertension must be under control. RESTRICTIONS a. Not covered for clients on renal dialysis! b. Clients scheduled for elective surgery must have a hemoglobin >10 and <13g/dl. c. Clients with chronic renal disease must have a baseline hematocrit (HCT) of <33%. (hemoglobin <11g/dl) d. Clients receiving chemotherapy must have a hemoglobin <10.5g/dl. e. Clients with anemia based on therapy with anti-retroviral therapies must have a baseline hematocrit of <33%. (hemoglobin <11g/dl f. If at 8 weeks the hemoblobin does not rise by 1gm/dl, discontinue therapy. g. When the hemoglobin is > 13, reduce the dose by 25% and continue therapy. h. If the hemoglobin exceeds 15, with hold therapy and reinitiate therapy when the hemoglobin falls below 12 **Duration** Blood transfusion (approve one time only) **Chronic Conditions** 60 day supply initially *Continued on next page*	W	OFF LABELED COVERAGE: NONE

<table>
<tr><th>DRUG</th><th>AGE</th><th>DIAGNOSIS</th><th>CRITERIA</th><th>PA</th><th>COMMENTS</th></tr>
<tr><td>Epoetin Alfa (Epogen, Procrit), Darbepoetin Alfa (Aranesp)</td><td></td><td></td><td>*continued from previous page*

After the initial 60 day approval, PA may be approved for 6 month increments if laboratory result indicate an improvement in either hematocrit or hemoglobin. Any transfusions received during this period should be noted in the documentation provided. Doses should be appropriately decreased if hematocrit exceeds 36%.

epoetin alfa: doses will not be approved for greater than 300U/kg three times a week or 60,000 units/week maximum.

darbepoetin alfa:
The recommended starting dose of darbepoetin is 0.45mcg/kg body weight, administered as a single IV or SQ
Titrate to not exceed a target hemoglobin concentration of 12g/dL.

Conversion from epoetin alfa to darbepoetin alfa:

<table>
<tr><th colspan="2">Estimated darbepoetin alfa starting doses (mcg/week) based on previous epoetin alfa doses (units/week)</th></tr>
<tr><th>Previous weekly epoetin alfa doses (units/week)</th><th>Weekly darbepoetin dose (mcg/week)</th></tr>
<tr><td>< 2500</td><td>6.25</td></tr>
<tr><td>2500 to 4999</td><td>12.5</td></tr>
<tr><td>5000 to 10,999</td><td>25</td></tr>
<tr><td>11,000 to 17,999</td><td>40</td></tr>
<tr><td>18,000 to 33,999</td><td>60</td></tr>
<tr><td>34,000 to 89,999</td><td>100</td></tr>
<tr><td>≥ 90,000</td><td>200</td></tr>
</table>
</td><td></td><td>Criteria effective April 15, 2002</td></tr>
</table>

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Tryptans' (5-HT_1 agonists)			Prior approval criteria for supplemental doses above cumulative limit of nine. 1. Clients who have failed prophylaxis from at least three of the listed drug categories and currently are on a fourth drug from table 1 may receive a prior approval. Dosage may be increased to no more than 18 doses of a tryptan per any 30 day period. **Table 1: Migraine Prophylaxis Medications** ● anticonvulsants: carbamazepine, valproic acid, gabapentin ● beta blockers: acebutololo, labetalol, metoprolol, nadolol, propanolol ● calcium channel blockers: verapamil ● SSRIs: citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline ● TCAs : amitriptyline, amoxapine, desipramine, doxepin, imipramine, nortriptyline, protriptyline, trimipramine Physicians are encouraged, unless contra-indicated, to place their clients who are on a 'tryptan' on metaclopramide which will increase the adsorption of the 'trypan'.	T	Quantity limit on 5-HT_1 agonists (tryptans) shall be set to nine cumulative doses in any 30 day period for migraine headache or cluster headache. Criteria effective July 1, 2002

Tracleer: see page 30.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Modafinil (Provigil)		narcolepsy multiple sclerosis	**Prior authorization must be obtained by physician.** **Labeled Indication:** improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy. Dose limited to 400mg qd. Psychosis has been reported at >600mg/day. Age: > 16 **Covered off Label Indication:** treatment to offset sedation related to multiple sclerosis treatment modalities; dose limited to 200mg qd. Six month maximum prior approval will be granted. Any of the following disorders precludes payment of modafinil. a. Antisocial Personality Disorder b. Schizo Typical Personality Disorder or Traits c. Borderline Personality Disorder or Traits d. Active Substance Abuse or Dependance	T	DEA: Schedule IV Cost for 30 days treatment at: 200mg = $145.53 400mg = $291.06 NOTE: There is a potential interactions with drugs that inhibit, induce or are metabolizaed by cytochrome P-450 isoenzymes including drugs such as carbamazepine, phenobarbitol, phenytoin, tricyclics. Criteria effective July 1, 2002.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
NSAIDS					Duplication limited to first duplication
COX-2 Inhibitors	>65		covered without PA		Duplication not allowed between COX-2 Inhibitors
COX-2 Inhibitors	0-64	analgesic	Covered for 10 days for pain management	T	telephone prior is required Duplication between NSAIDS not allowed
COX-2 Inhibitors		antiinflammatory -	covered as an anti-inflammatory for clients having documented or diagnosed: GERD; Barrett's Syndrome; peptioc ulcer; gastro hypersecretory conditions; or documented gastric bleeding caused by other NSAIDS	W	Covered if client on concomitant antigoagulant therapy Covered if client on concomitant oral corticosteroid therapy Duplication not allowed between COX-2 Inhibitors Dosing limited to labeled amounts

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
ACTIQ		covered only for diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature		W	correct ICD.9 must be written on prescription by prescriber. Pharmacist must enter that ICD.9 into the diagnoses field Absolute maximum cumulative limit of 120 units per 30 day period.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
morphine long acting formulations		a. chronic non-malignant pain. b. diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, or Pagent's Disease		W	a. Cumulative limit of 90 capsules/tablets for any strengths per 30 days b. correct ICD.9 code must be written on prescription by prescriber for diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature on prescription allows full access.
Duragesic 25mcg, 50mcg, 75mcg.		a. chronic non-malignant pain. b. diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, or Pagent's Disease		W W	a. Cumulative limit of 15 patches for any combination of strengths per 30 days. b. Correct ICD.9 must be written on prescription by prescriber for diagnoses of malignant neoplasms, carcinoma in situ, or neoplasms of unspecified nature on prescription allows full access. 100mcg patch no covered for chronic non-malignant pain.
OxyContin		a. chronic non-malignant pain. b. diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, or Pagent's Disease		W	a. OxyContin up to 100mg daily or 90 tablets per any 30 day period. b. Correct ICD.9 must be written on prescription by prescriber for diagnoses of malignant neoplasms, carcinoma in situ, or neoplasms of unspecified nature on prescription allows full access.
Methadone		a. chronic non-malignant pain. b. diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, or Pagent's Disease		W	a. 50mg per day maximum b. Correct ICD.9 must be written on prescription by prescriber for diagnoses of malignant neoplasms, carcinoma in situ, or neoplasms of unspecified nature on prescription allows full access.

DRUG	AGE	DIAGNOSIS	CRITERIA	PA	COMMENTS
Non Sedating Antihistamines, excepting loratadine formulations			Criteria for prior approval for these legend drugs includes: FAXed copy from patient charts documenting failure on loratadine due to specified adverse drug reaction or failure of efficacy while patient is on loratadine.	W	Over-the-counter loratadine formulations covered without a prior approval for up to 30 doses/30 days non-sedating antihistamines limited to 30 doses/30 days.
Atypical Antipsychotics	0-6	See attachment for covered ICD.9 code			Correct ICD9 diagnosis must be written on prescription
	7-19	See attachment for covered ICD.9 code			Correct ICD9 diagnosis must be written on prescription
	>19	See attachment for covered ICD.9 code			Correct ICD9 diagnosis must be written on prescription

PRESCRIPTION LIMIT			
Effective January 1, 2002, Medicaid limits coverage of prescriptions to a maximum of seven prescriptions a month for most adult clients, including nursing home patients. The limit includes scripts for over-the-counter medications. Medicaid exempts certain clients and certain drug classes from the prescription limit. Reference: Utah Medicaid Provider Manual for Pharmacy Services, SECTION 2, Chapter 2 - 1, Prescriptions Limited to Seven a Month	Children under age 21 and pregnant women are exempt from the prescription limit. There is no limit on the number of prescriptions that may be filled for children under age 21 and pregnant women.	Drug types listed below are not subject to the seven-prescription limit: A4A - hypotensives - vasodilator A4B - hypotensives - sympatholytic A4C - hypotensives - ganglionic blockers A4D - hypotensives, ACE blocking type A4E - hypotensives, veratrum alkaloids A4F - hypotensives, angiotensin receptor antagonist A4Y - hypotensives, miscellaneous A9A - calcium channel blocking agents C4G - insulins C4K - hypoglycemics, insulin-release stimulant type C4L - hypoglycemics, biguanide type (non-sulfonylureas) C4M - hypoglycemics, alpha-glucosidase inhib. Type (N-S) M0E - antihemophilic factor VIII M0F - antihemophilic factor IX M4E - lipotropics (cholesterol lowering agents) R1M - loop diuretics V1A - alkylating agents V1B - antimetabolites V1C - vinca alkaloids V1D - antibiotic antineoplastics V1E - steroid antineoplastics V1F - antineoplastics, miscellaneous W5B - HIV - specific W5C - HIV - specific, protease inhibitors	Generally, a pregnant woman will not have a co-pay message by her name on the Medicaid Card. If there is a co-pay message by the woman's name, encourage her to report the pregnancy to her Medicaid eligibility worker. The worker can change her co-pay status to exempt. Reference: Utah Medicaid Provider Manual, SECTION 1, GENERAL INFORMATION, Chapter 6 - 8, Exceptions to Prohibition on Billing Patients, item 3, Medicaid Co-payments.

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